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Fax Cover Sheet

Date: 19 Nov 2003

To: Michelle Walters / Richard Peet	From: Examiner A. Sheikh
Application/Control Number: 09/521,139	Art Unit: 1615
Fax No.: (202) 672-5399	Phone No.: (303) 308-4429
Voice No.: (202) 672-5370	Return Fax No.: (703) 746-9256
Re: office action (12/23/02) paper#5	CC:
<input type="checkbox"/> Urgent <input checked="" type="checkbox"/> For Review <input type="checkbox"/> For Comment <input type="checkbox"/> For Reply <input checked="" type="checkbox"/> Per Your Request	

Comments:

Attached is a Courtesy Copy of the Non-Final Office Action
filed 12/23/02 for your review. The previous action,
an Election Restriction Requirement
filed 5/13/2002 for complete
review.

Any questions?

please call. Thanks.

Yanira A. Sheikh
11-19-03

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Number of pages including this page

STATEMENT OF CONFIDENTIALITY

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UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/521,139	03/08/2000	Steven J. Prestrelski	OPF 25.20	1246

7590 12/23/2002

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1615	5

DATE MAILED: 12/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/521,139	PRESTRELSKI ET AL.
	Examiner	Art Unit
	Humera N. Sheikh	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 October 2002 (paper no. 4) .

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) 11-26 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-10 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____ .
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .

4) Interview Summary (PTO-413) Paper No(s) _____ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____ .

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the request for an Extension of Time (4 months) and the Response to Requirement for Restriction, both filed 10/14/02.

Claims 11-26 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Claims 1-10 are pending. Claims 1-10 are rejected.

Claim Objections

Claim 5 is objected to because of the following informalities: In claim 5, line 27, the term, “poly(carprolactone)” is misspelled and should be changed to “poly(caprolactone”). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 in lines 1-4 recites the phrase, "a *first set of particles* comprising the biologically active agent in association with a first sustained release material and a *second set of particles* comprising the biologically active agent in association with a second sustained release material". The claim is indefinite because it is unclear and confusing as to what the applicant is intending to convey. (For instance, are the sets of particles the same or different in nature). Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4 and 7-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Bellhouse et al. (US Pat. No. 5,630,796, collectively, “Bellhouse”).

Bellhouse discloses drug-containing particles that are delivered through a needleless syringe, wherein the particles comprise a therapeutic agent in controlled doses into the skin and wherein the particles have a particle size in the range of 0.1 to 250 microns, a diameter of up to 100 microns and a density in the range of 0.1 to 25 g/cm³ (see reference col. 1, lines 30-44); (col. 4, lines 13-50).

Claims 1-4 and 7-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Bellhouse et al. (US Pat. No. 5,630,796, collectively, “Bellhouse”).

Bellhouse discloses drug-containing particles that are delivered through a needleless syringe, wherein the particles comprise a therapeutic agent in controlled doses into the skin and wherein the particles have a particle size in the range of 0.1 to 250 microns, a diameter of up to 100 microns and a density in the range of 0.1 to 25 g/cm³ (see reference col. 1, lines 30-44); (col. 4, lines 13-50).

**Claims 1-8 are rejected under 35 U.S.C. 102(a) as being anticipated by
Edwards et al. (US Pat. No.5,874,064, collectively, “Edwards”).**

Edwards discloses improved aerodynamically light particles for drug delivery comprising particles capable of a long-term release of a therapeutic agent, having a tap (envelope) density less than 0.4 g/cm³ and a mass mean diameter between 5 microns and 30 microns. The particles may be formed of biodegradable and biocompatible materials such as biodegradable polymers, proteins, or other water-soluble materials (see Abstract); (col. 3, lines 12-40); (col. 5, lines 8-33).

**Claims 1-8 are rejected under 35 U.S.C. 102(e) as being anticipated by
Edwards et al. (US Pat. No.5,874,064, collectively, “Edwards”).**

Edwards discloses improved aerodynamically light particles for drug delivery comprising particles capable of a long-term release of a therapeutic agent, having a tap (envelope) density less than 0.4 g/cm³ and a mass mean diameter between 5 microns and 30 microns. The particles may be formed of biodegradable and biocompatible materials such as biodegradable polymers, proteins, or other water-soluble materials (see Abstract); (col. 3, lines 12-40); (col. 5, lines 8-33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellhouse et al. (US Pat. No. 5,630,796, collectively, "Bellhouse").

Bellhouse discloses drug-containing particles that are delivered through a needleless syringe, wherein the particles comprise a therapeutic agent in controlled doses into the skin and wherein the particles have a particle size in the range of 0.1 to 250 microns, a diameter of up to 100 microns and a density in the range of 0.1 to 25

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g/cm³ (see reference col. 1, lines 30-44); (col. 4, lines 13-50). Bellhouse also teaches a needleless syringe for transdermal delivery comprising particles of a therapeutic agent wherein the syringe may be used for routine delivery of drugs (i.e., insulin for the treatment of diabetes), used for immunization and for the delivery of slow-release drugs (i.e., painkillers and contraceptives). The needleless syringe may also be used for the delivery for genetic material into living skin cells, muscle, blood or lymph and organs (col. 1, lines 45-54). The needleless syringe can also be used for surgical procedures to deliver drugs and biologics to organ surfaces, solid tumors and/or to surgical cavities.

The instant invention is drawn to a particulate composition suitable for administration to a subject by means of a needleless syringe, wherein the composition comprises particles that comprise a biologically active agent and a sustained-release material wherein the particles have a mean mass diameter of from about 0.1 to about 250 microns and an envelope density of from about 0.1 to about 25 g/cm³.

Bellhouse teaches a drug-containing particulate composition delivered by a needleless syringe wherein the particles comprise a therapeutic agent in a slow-release rate and he explicitly teaches that the drug-containing particles have a particle size in the range of about 10 to 250 microns and a density in the range of 0.1 to about 25 g/cm³ (see claim 1).

There is no significant distinction observed between the prior art and the instant invention since the prior art similarly teaches such a particulate composition comprising

an active agent wherein the particle density (0.1 to about 25 g/cm³) and particle size or diameter (~ 10-250 microns), which clearly read on the applicant's instant claims.

Bellhouse refers to the particles as having a particle *diameter* and does not specifically state, "*mean mass aerodynamic diameter*", however since the particles of Bellhouse are intended for a similar purpose and are formulated in a similar manner as the applicant, one of ordinary skill familiar in the pharmaceutical art would interpret the particle diameter as taught by Bellhouse, as referring also to the mean mass diameter. Furthermore, since the formulation of the particles of the prior art is similar to those of the instant invention, the properties would also be the same. The expected result would be a particulate composition with a predetermined mass diameter for the desirability of obtaining the best possible outcome.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bellhouse et al. (US Pat. No. 5,630,796, collectively, "Bellhouse") in view of Tice et al. (US Pat. No. 4,530,840, collectively, "Tice").

Bellhouse while teaching a drug-containing particulate composition delivered by a needleless syringe wherein the particles comprise a therapeutic agent in a slow or controlled drug release rate, is deficient only in the sense that he does not teach the specified sustained-release materials (poly-lactide, glycolide, caprolactone, hydroxybutyrate, etc) as claimed by the applicant.

Tice teaches an injectable long-acting, slow-release microparticle formulation for the delivery of anti-inflammatory agents comprising suitable polymeric matrix materials, which include poly (glycolic acid), poly-d, L-lactic acid, copolymers thereof, polycaprolactone, poly (lactic acid-caprolactone) and the like (see reference col. 2, lines 16-55). Table I demonstrates a method for the preparation of methylprednisolone acetate microparticles with a poly (d, L-lactide) excipient (col. 5, line 52 through col. 6, line 68).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made and there is ample motivation provided by the prior art to incorporate the suitable polymeric matrix materials such as poly (glycolic acid), poly-d, L-lactic acid, copolymers thereof, polycaprolactone, poly (lactic acid-caprolactone) and the like, because the prior art teaches that these polymeric matrix materials are suitable polymeric materials for obtaining biocompatibility and biodegradability with the human body.

Further motivation is provided by the prior art since Tice teaches a slow-release injectable microparticle formulation wherein an appropriate selection of polymeric materials yields a microparticle formulation exhibiting both diffusional and biodegradation release properties. The expected result would be a slow-release, biodegradable and biocompatible microparticle formulation, as similarly desired by the applicant.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. (US Pat. No.5,874,064, collectively, "Edwards").

Edwards discloses improved aerodynamically light particles for drug delivery comprising particles capable of a long-term release of a therapeutic agent, having a tap (envelope) density less than 0.4 g/cm³ and a mass mean diameter between 5 microns and 30 microns. The particles may be formed of biodegradable and biocompatible materials such as biodegradable polymers, proteins, or other water-soluble materials (see Abstract); (col. 3, lines 12-40); (col. 5, lines 8-33). The therapeutic agent can be selected from the group consisting of proteins, polysaccharides, lipids, nucleic acids and combinations thereof (claim 13). The aerodynamically light particles may be fabricated or separated to provide a particle sample with a preselected size distribution. For example, greater than 30%, 50%, 70% or 80% of the particles in a sample can have a diameter within a selected range of at least 5 microns. The selected range within which a certain percentage of the particles must fall may for example, between about 5 and 30 microns, or optionally between 5 and 15 microns (col. 4, lines 10-47). The particles may be formed from any biocompatible biodegradable polymer, copolymer or blend, which is capable of forming particles having a tap (envelope) density less than about 0.4 g/cm³ (col. 6, lines 39-43). Edwards teaches that bulk-eroding polymers can be used, which include polyglycolic acid (PGA) or polylactic acid (PLA) or copolymers thereof. Various other polymers are also taught (col. 6, line 50 through col. 7, line2). Examples 5 and 6

demonstrate the use of two particle types using light and non-light particles (cols. 15 & 16).

The instant invention is drawn to a particulate composition suitable for administration to a subject by means of a needleless syringe, wherein the composition comprises particles that comprise a biologically active agent and a sustained-release material wherein the particles have a mean mass diameter of from about 0.1 to about 250 microns and an envelope density of from about 0.1 to about 25 g/cm³.

The prior art teaches improved aerodynamically light particles for drug delivery comprising particles capable of a long-term release of a therapeutic agent, having a tap (envelope) density less than 0.4 g/cm³ and a mass mean diameter between 5 microns and 30 microns.

There is no significant distinction observed between the instant invention and the prior art since Edwards teaches a particulate composition comprising particles having a therapeutic agent contained therein in a controlled or long-term release formulation comprising the applicant's claimed ranges of mass mean diameter and envelope density. Furthermore, there is ample motivation provided by the prior art to obtain particles having a mean mass diameter of from about 0.1 to about 250 microns and an envelope density of from about 0.1 to about 25 g/cm³ because Edwards teaches particles having a tap (envelope) density less than 0.4 g/cm³ and a mass mean diameter between 5 microns and 30 microns, which reads on the applicant's claimed ranges.

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate a particulate composition comprising aerodynamically light particles containing a drug or therapeutic agent with biodegradable and biocompatible sustained release materials having a tap density less than 0.4 g/cm³ and a mass mean diameter between 5 microns and 30 microns because they particles are then capable of a longer term release of a therapeutic agent and (due to the relatively low tap density) subsequently undergo slow degradation and drug release. The expected result would be improved aerodynamically light particles for drug delivery offering effective biodegradable and biocompatible capabilities.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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